1.Rejection of claim 7 under 35 U.S.C. §112, 2nd paragraph

The Official Action states that claim 7 is rejected under 35 U.S.C. §112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Official Action states, in relevant part, the following:

> Claim 7 is rejected because the claims are self-conflicting. Pharmaceutical composition by definition must be effective yet non-toxic.
> It is recommended that "therapeutically effective amount" be incorporated in the claim.

RESPONSE

Applicant respectfully traverses this rejection. Applicant respectfully submits that the phrase "pharmaceutical composition" is not self-conflicting because the absence of the phrase "therapeutically effective amount" cannot generate a conflict.

The Examiner has not supported her position with any U.S. case law or MPEP section which requires such wording in a pharmaceutical composition claim. Further, applicant submits that many patents have issued with pharmaceutical composition claims that do not contain this language which has been recommended by the Examiner. In this regard, applicant respectfully directs the Examiner's attention to the following

patents:

1. US Patent No. 6,818,642
2. US Patent No. 6,924,305
3. US Patent No. 6,936,622
4. US Patent No. 6,962,941
5. US Patent No. 7,022,696 and
6. US Patent No. 7,060,716.

There are, of course, many more patents than those listed which contain pharmaceutical composition claims that do not contain the phrase "therapeutically effective amount". The patent numbers are simply provided for the Examiner's convenience.

Accordingly, since claim 7 is clear and definite in its present form, applicant respectfully requests that the Examiner reconsider and withdraw this rejection of claim 7.

2. Rejection of Claims 10-11 under 35 U.S.C. §112, 1st paragraph

The Official Action states that claims 10-11 are rejected under 35 U.S.C. §112, 1st paragraph for lack of enablement. In particular, the Official Action states that "it is not seen where the instant claim 1[sic], for treating chronic

inflammatory disease of peripheral organs and the central nervous system (CNS) disease, have been enabled by the instant specification."

RESPONSE

Applicant respectfully traverses this rejection of claims 10-11. Claims 10-11 are clearly enabled by the instant specification because applicant has demonstrated a nexus between 1) the effectiveness of the compounds of formula I to inhibit the inducible nitric oxide synthase (iNOS) and 2) the common knowledge in the art that iNOS inhibition is useful in treating acute and chronic inflammatory diseases.

First, applicant respectfully submits that claim 11 is directed to the treatment of an acute inflammatory disease and claim 10 is directed to the treatment of a chronic inflammatory disease of peripheral organs and the CNS. The Examiner stated on page 4 of the Official Action that "[t]he instant invention is drawn to a method of treating chronic inflammatory disease of peripheral organs and the central nervous system (CNS) using the compounds of claim 1" which does not accurately reflect the subject matter of both pending method of treatment claims.

Regarding the substance of the rejection, applicant

respectfully points out the following to the Examiner. The instant specification contains data in Table A on page 24 which clearly demonstrates that the presently claimed and allowable compounds inhibit inducible nitric oxide synthase (iNOS). Further, it is well known in the art that the inhibition of iNOS and treatment of acute and chronic inflammatory diseases, as presently claimed, are related. In this regard, the specification contains numerous references to publications demonstrating the relationship between inhibition of iNOS and the treatment of acute and chronic inflammatory diseases. See pages 20-21. In addition to these references explicitly outlined in the present specification, applicant has submitted herewith an Information Disclosure Statement citing seventeen (17) references, at least seven of which demonstrate the relationship between iNOS inhibition and treatment of acute and chronic inflammatory diseases. The relevant portions of seven of the attached IDS references are briefly discussed herein below.

Hansel et al. describe that inhibition of iNOS has therapeutic potential for asthma in addition to a range of inflammatory diseases involving other organ systems. See page 1300, last sentence in right column.

In Cuzzocrea et al., a study is described showing that a potent and selective inhibitor of iNOS activity attenuates the degree of chronic inflammation and tissue damage associated with collagen-induced arthritis in mice. See abstract, last paragraph, 1st sentence.

Ohtsuka et al. state that excessive NO production is closely related to inflammatory diseases and suppression of excess NO formation in participating cells may be helpful in improving disease status. See abstract, left column. In this respect, it may be noted that iNOS is an enzyme that generates NO from arginine. Accordingly, inhibition of the iNOS, as done by the compounds of the present invention, reduces the NO level in the participating cells, thus, improving inflammatory diseases.

Tinker et al. describe compounds which are iNOS inhibitors and which show efficacy in acute and chronic animal models of inflammatory diseases. See abstract.

According to Kankuri et al., treatment with a selective iNOS inhibitor reduced formation of edema, neutrophil infiltration and macroscopic inflammation damage in experimentally induced acute colitis in the rat. See abstract.

Liu et al. state that recent studies have shown that the

selective inhibitors of iNOS can play an important role inter alia in chronic inflammation. See page 1052, right column, first paragraph, last sentence.

Salvemini et al. conclude that selective inhibitors of iNOS are clearly anti-inflammatory agents. See last paragraph of abstract.

Accordingly, a person of ordinary skill in the art would be enabled by the instant specification, combined with the common knowledge in the art, to practice the presently claimed invention.

If the enablement rejection of the Examiner is upheld, it would mean that an inventor of an innovative new drug would have to wait to file her patent application until human clinical trials were performed. Such a conclusion is obviously incorrect. A reasonable correlation between a compound's activity and its asserted use, as demonstrated by applicant with the data present in the instant specification, and the literature references filed herewith, is clearly enough to properly demonstrate enablement of the presently claimed methods.

Accordingly, claims 10-11 comply with the requirements of 35 U.S.C. §112, 1st paragraph. As such, applicant respectfully

requests that the Examiner reconsider and withdraw this rejection of claim 10-11.

3. Allowable Subject Matter

The Examiner has indicated that claims 1-5 are free of the prior art and are allowable.

Applicant thanks the Examiner for this indication of allowable subject matter and respectfully submits that all outstanding rejections have been overcome with the arguments submitted herewith.

CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 7 and 10-11, and to allow all of the claims pending in this application to proceed to grant.

If the Examiner has any questions or wishes to discuss this matter, she is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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